Papahadjopoulos, et al. Application No.: 09/076,618 Page 2

REMARKS

Amendment

The amendment to claim 48 adds no new matter. The polycation in claim 48 is clearly intended to be "organic" since claim 49, which is dependent on claim 48, limits claim 48 by specifying that "said organic polycation" is selected from a group of identified polycations. The use of the word "said" clearly implies that the polycation referred to in claim 48 is organic. Accordingly, omission of the word "organic" in claim 48 is clearly inadvertent.

Response to Restriction Requirement

Restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. MPEP § 803.01. Applicants respectfully submit that examining the claims of the different Groups together would not place an undue burden on the Examiner. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome.

The Action asserts that in this case, the restriction of Group I from Group II is warranted because the polycation of Group I is more narrowly defined and because the complexes of Group II are limited to pharmaceuticals. Following the amendment discussed above, there is no longer a difference between the polycations of Groups I and II, and that rationale is accordingly no longer available for separating the claims into two groups.

Papahadjopoulos, et al. Application No.: 09/076,618

Page 3

The second asserted rationale is that Group II is limited to pharmaceuticals and Group I is not. Applicants respectfully note that the difference between, for example, the lipid:nucelic acid complex of claim 39 in Group I and the pharmaceutical composition of the lipid:nucleic acid complex in Group II is the presence in the latter of a "pharmaceutically acceptable carrier," such as sterile saline. As searches are traditionally conducted by looking at the active components (here, the lipid:nucleic acid complexes) rather than the sterile saline or other pharmaceutically acceptable carrier, it cannot reasonably be maintained that examination of the claims of Group II present an undue burden on top of the examination of the same lipid:nucleic acid complexes as in Group I due simply to the presence of the carrier.

The Action further asserts that treating kits of the components as a separate group is warranted because the components of the kits are not complexes but merely collections of components and, "[a]s such, they are chemically distinct from complexes."

Action, at pages 2-3. Applicants note first that "chemical distinctness" does not appear among the Examiner's own list of approved reasons for finding inventions distinguishable on page 2 of the Action. Moreover, the point of the kits is to permit the assemblage of the lipid:nucleic acid complexes. There would appear to be little reason to assemble the kits if not to produce the complexes. Accordingly, the search of the complexes is largely congruent with the search respecting the kits and should not impose an undue burden. The joinder of Groups I, II, and III is therefore appropriate.

CONCLUSION

If the Examiner has any questions regarding this Response, or believes a telephone conference would expedite prosecution of this application, she is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

Laurence J. Hyman Reg. No. 35,551

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, California 94111-3834

Tel: (415) 576-0200 Fax: (415) 576-0300

LJH SF 1013331 v1